UNITED STATES DISTRICT COURT **SOUTHERN DISTRICT OF TEXAS**

United States ex rel. Veterans First Medical Supply, LLC, Relator vs. Tactile Systems Technology, Inc., Defendant.	Case No. H-18-2871

THIRD AMENDED COMPLAINT

I. INTRODUCTION

1. This is an action by Relator Veterans First Medical Supply LLC (hereafter "VFMS") to recover damages and civil penalties for false statements and claims made or caused to be made by Defendant Tactile Systems Technology, Inc. (hereafter "Defendant" or "Tactile Medical") in violation of the False Claims Act, 31 U.S.C. §3729 (the "FCA") and unlawful retaliation in violation of §3730(h). Relator seeks actual damages, treble damages and penalties under the False Claims Act for the false claims for reimbursement for Defendant's pneumatic compression pump products. In addition, Relator VFMS seeks damages under the anti-retaliation provisions of the False Claims Act.

2. At issue are false claims and statements by Defendant to the United States under the Medicare and Medicaid Programs for goods or services procured by or through various major health care facilities and hospitals in this District and throughout the United States, including the

U.S. Department of Veterans Affairs ("VA") Medical Center in Houston, Texas; St. Luke's Hospital, The Woodlands, Texas ("The Woodlands Hospital"); and Methodist Hospital in Sugarland, Texas ("Sugarland Hospital") (collectively referred to as "the Hospitals"). No claims are asserted in this Complaint against the Hospitals or any of their health care providers.

3. These claims arise from Defendant promoting the sale of medical equipment to the Hospitals through unlawful marketing schemes, which expose the Hospitals to liability and compromise Medicare and Medicaid in violation of Federal Law.

II. PARTIES

4. Relator VFMS is a Texas limited liability company doing business primarily in this District. It is wholly owned by Jody Allen, a service-disabled American Veteran. VFMS' acts through Allen and his colleague, Bill Gibbs. All factual allegations contained in this Complaint are based on the personal knowledge of Allen and Gibbs.

5. Defendant Tactile Systems Technology, Inc., doing business as "Tactile Medical" is a Delaware corporation with its principal place of business at 1331 Tyler Street NE, Suite 200, Minneapolis, Minnesota. It is registered to do business in Texas and may be served with process by service on its registered agent, Corporation Service Company, 211 E. 7th Street, Suite 620, Austin, Texas 78701. Defendant's websites are www.tactilemedical.com and www.flexitouch.com.

III. JURISDICTION AND VENUE

6. This Court has in personam jurisdiction over Defendant under 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because Defendant can be found in and transacts the business that is the subject matter of this lawsuit in this District.

7. Venue is proper in the United States District Court for the Southern District of Texas, pursuant to 28 U.S.C. § 1391(b) and (c) and 31 U.S.C.§ 3732(a), because Defendant is registered to do business in this District. Also, VFMS' principal place of business is in this District and many of the acts that form the basis of this Complaint occurred in this District.

8. This case is not based on a public disclosure. Relator VFMS is an original source. VFMS' Jody Allen and Bill Gibbs have direct, personal knowledge of the matters alleged herein. Additionally, before filing this suit, VFMS voluntarily disclosed all material, relevant facts relating to this case to the United States.

IV. FACTUAL BACKGROUND

9. According to its website, Defendant manufactures and markets pneumatic compression pumps and other devices for the treatment of chronic venous insufficiency (CVI) and lymphedema, conditions which disproportionately impact the elderly and can be deadly if left untreated.[1]

10. CVI is an abnormality of the venous wall and valves which leads to obstruction or "reflux" of blood flow in the veins in a patient's lower extremities. CVI is distinguished from lymphedema in that lymphedema occurs when the lymphatic system is not able to clear fluid from the interstitial tissues of the body and return it to the bloodstream via a system of lymphatic vessels and lymph nodes.[2]

[1] *See* www.tactilemedical.com.
[2] *See* CMS "Decision Memo for Compression Pumps for Venous Insufficiency (CAG-00075N)", at https://www.cms.gov/medicare-coverage-database, attached as Exhibit "A".

11. Medicare has covered pneumatic compression pumps for the treatment of lymphedema since at least 1986[3]. In 1995, Medicare expanded coverage of pneumatic compression pumps for the treatment of CVI that results in ulceration of the lower extremity after standard wound care treatment had been tried unsuccessfully for 6 months.[4] This was the result of findings that leg ulcers constitute a major clinical problem for the elderly, with only 50% of such ulcers healing within 4 months. Indeed, CVI was found to be a "lifelong condition" requiring use of compression stockings and other measures "continuously for the rest of the patient's life".[5] Thus, a compression pump may speed up the healing process.

12. According to the Centers for Medicare and Medicaid Services Decision Memo dated October 17, 2001[6]:

> [C]urrent policy covers the use of pneumatic compression pumps for patients with refractory edema from [CVI] with significant ulceration of the lower extremities that have received standard therapy but have failed to heal after 6 months of continuous treatment. After review of all available published literature, we have found sufficient evidence to show that standard care for the treatment of [CVI], which results in ulceration, can be successfully treated by elevation, exercise and compression therapy. Therefore, we conclude that our current policy is appropriate and will not be changed at this time.

13. Under CMS guidelines requiring monitoring of an ulceration, a claim for payment for a pneumatic compression device by Medicare requires the physician to complete a "certificate of medical necessity."

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[3] *See* Centers for Medicare and Medicaid Services ("CMS"), "Decision Memo for Lymphedema Pumps (CAG-00016N), at https://www.cms.gov/medicare-coverage-database, attached as Exhibit "B".
[4] *Id*. at Exhibit A.
[5] *Id*.
[6] *Id*.

14. The CMS promulgated form, "CERTIFICATE OF MEDICAL NECESSITY CMS-846 — PNEUMATIC COMPRESSION DEVICES" OMB Form No. 0938-0679 (Expires 02/2020)[7] contains the following required certification:

> I certify that I am the treating physician identified in Section A of this form. I have received Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.

15. Additionally, the physician is required to provide a "narrative description of all items, accessories and options ordered" and provide details of the "supplier's charge" and "Medicare Fee Schedule Allowance for each item, accessory, and option."[8]

16. Defendant solicits prescriptions/orders for a specific line of Durable Medical Equipment (DME) known as Compression Therapy Products (CTPs) used for the treatment of Lymphedema, wound care management and other chronic venous conditions. Prescription of CTPs requires a physician's certification of medical necessity, as alleged herein.

17. The CTP must be delivered to the patient's home in order to set up the equipment, provide training to the patient and/or caregiver on the proper use of the product, to ensure a proper fit of the garments used for treatment and to assure the safety and comfort of the patient in the home setting in order to receive the maximum medical benefit of this expensive, prescribed medical equipment.

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[7]Required Certificate of Medical Necessity, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS846.pdf [last accessed June 4, 2018], attached as Exhibit "C".

[8] *Id.*

18. To legally sell and distribute its CTPs to Medicare/Medicaid recipients, Defendant must comply with the rules and regulations of CMS. Similarly, the providers who prescribe Defendant's products must comply with CMS guidelines and certify their compliance. Additionally, it must comply with 42 USC §1320a-7b, but it does not.

19. Defendant is engaged in fraudulent conduct because it knowingly engages in soliciting, receiving, offering and/or paying remuneration to induce or reward referrals for items or services reimbursed by Federal health care programs that violate the FCA in several ways:

a. Defendant regularly, routinely and systematically offers to pay and does pay remuneration to Hospital clinical staff to induce Hospital physicians to prescribe Defendant compression pump equipment to the exclusion of all other suppliers of such equipment;

b. Defendant regularly, routinely and systematically offers to pay and does pay remuneration to Hospital physicians in the form of honoraria, endorsement fees and other payments to induce them to prescribe Defendant compression pump equipment to the exclusion of all other suppliers of such equipment; and

c. Defendant regularly, routinely and systematically pays or offers to pay remuneration to the staff of Veterans Hospital in Houston in order to induce it to ignore Relator VFMS' status as a Service-Disabled Veteran Owned Small Business and to order Defendant's CTP equipment to the exclusion of Relator VFMS.

20. According to its most recently filed 10-K, Defendant represents to the SEC that it "possess[es] a unique, scalable platform to deliver at-home healthcare solutions throughout the United States." In fact, its "evolving home care delivery model" depends on the "over 470" hospital clinicians that are Defendant "contractors" but who also are employees of the hospitals

where Defendant's products are prescribed and paid for by Medicare, Medicaid, and Insurance Companies.

21. Defendant knows that its use of these "contractors" is unlawful and poses substantial "risks related to our business." As stated in Defendant's 10-K:

> A reclassification of our independent contractor home trainers by tax authorities could require us to pay retroactive taxes and penalties, which could have a material adverse effect on our business, financial condition and operating results. We contract with over 470 licensed healthcare practitioners as home trainers, who educate our patients on the proper use of our solutions. Because we consider these licensed practitioners to be independent contractors, as opposed to employees, we do not withhold federal or state income or other employment related taxes or make federal or state unemployment tax or Federal Insurance Contributions Act payments. Our contracts with these independent contractors obligate them to pay these taxes. The classification of healthcare practitioners as independent contractors depends on the facts and circumstances of the relationship. In the event federal or state taxing authorities determine that the healthcare practitioners are employees, our business may be adversely affected and subject to retroactive taxes and penalties. Under current federal tax law, a safe harbor from reclassification, and consequently retroactive taxes and penalties, is available if our current treatment is consistent with a long-standing practice of a significant segment of our industry and if we meet certain other requirements. If challenged, we may not prevail in demonstrating the applicability of the safe harbor to our operations. Further, in the future there could be changes to the laws and rules in this area, including new or different interpretations or guidance, or the modification or elimination of the safe harbor. Any such changes in the law, rules or safe harbor, or new or different interpretations or guidance, could impact our classification of healthcare practitioners as independent contractors, which could have a material adverse effect on our business, financial condition and results of operations.

22. Moreover, Defendant is well aware that its regular, routine and systematic payment of remuneration to its "contractors" is problematic and poses an existential risk to its very business model:

> ***We are subject to additional federal, state and foreign laws and regulations relating to our healthcare business; our failure to comply with those laws could have an adverse impact on our business.***

We are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could adversely impact our business. Healthcare fraud and abuse and health information privacy and security laws potentially applicable to our operations include:

[T]he federal Anti-Kickback Statute, which applies to our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, soliciting, receiving, offering or providing remuneration, whether directly or indirectly and overtly or covertly, intended to induce the referral of an individual for (i) the furnishing or the arranging for the furnishing of items or services reimbursable under a federal healthcare program, such as Medicare or Medicaid; or (ii) the purchase, lease or order of, or the arrangement or recommendation of the purchasing, leasing or ordering of, of an item or service reimbursable under a federal healthcare program. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;

[F]ederal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government, knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government or knowingly offering remuneration to influence a Medicare or Medicaid beneficiary's selection of health care providers. The government may assert that a claim, including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes[.]"

Defendant's December 31, 2017 Form 10-K, page 46.[9] [emphasis added]

[9] Available at https://www.sec.gov/Archives/edgar/data/1027838/000155837018001091/tcmd-20171231x10k.htm [last accessed June 5, 2018]

Illegal Remuneration Paid to Doctors

23. From June 2011 through at least May 2018, Defendant systematically violated the anti-kickback provisions of 42 U.S.C. §1320a-7b(2)(A), which prohibits the payment of remuneration to induce referrals of items or services covered by Medicare, Medicaid, and other federally-funded programs.

24. Defendant violated 42 U.S.C. §1320a-7b(2)(A) by paying doctors to be "advisors", to be "paid spokespersons" and to speak about its pneumatic compression devices at events that were often little or nothing more than social occasions for the doctors. One renowned and well-respected Houston area physician, Ulysses Baltazar, M.D., director of the wound care department of Sugarland Hospital, admitted this to Allen. Specifically, Dr. Baltazar stated to Allen in 2017 that he and his staff received free lunches from, and he was a "paid spokesman" and a paid "advisor" to the Defendant. This statement was made by Dr. Baltazar to Allen when he explained to Allen why all pneumatic compression devices were then being and would continue to be ordered from Defendant and not from VFMS or other competitors of Defendant.

25. The payments to the doctors were, in reality, kickbacks to the speakers and attendees to induce them to write prescriptions for Defendant's devices.

26. Defendant made payments to doctors for purported speaker programs that either did not occur at all or that had few or no attendees.

27. As a consequence of its violations of the Anti-Kickback Statute, Defendant has caused the submission of numerous false claims for durable medical equipment (DME) to federal health care programs, including Medicare, Medicaid and the Department of Veterans Affairs health care program, resulting in over $100 million in sales revenue, much of it from federal

reimbursements. In the case of the Hospitals, Defendant's strategy has paid off, resulting in Defendant obtaining overwhelming market dominance in the United States.

28. The conduct alleged herein is in direct violation of 42 USC 1320a-7b and clearly articulated CMS conflict of interest policies as defined in FAR 3.1101 and as articulated in FAR 2.101 and FAR 9.502. Defendant's unlawful conduct caused false claims to be made to and paid by the federal health care programs.

Illegal Remuneration Paid to Hospital Staff

29. Defendant's illegal kickbacks are paid to employees of the hospitals from which Defendant's CTPs are prescribed. Buried in Defendant's SEC filings is the admission that it contracts with "over 470" certified clinicians that do the in-home set-up and patient training. Not stated, however, is that these clinicians are employees of the very same facilities from which Defendant solicits prescriptions/orders from. In no case are these persons authorized to act as purchasing agents for the Hospitals or the health care providers who prescribed Defendant's CTPs. Allen and Gibbs know this because each of them are in regular contact with these "contractors" in the course of VFMS' attempts to compete with the Defendant in the marketplace. However, Defendant does not disclose that fact in its 10-K or to Medicare, Medicaid or to the VA, The Woodlands Hospital or Sugarland Hospital.

30. Defendant solicits employees of the hospitals by various means, including by targeted, direct mail pieces in which Defendant advertises that it is "seeking contract trainers." Attached hereto as Exhibit "D" is a true and correct copy of a Tactile Medical solicitation.

31. Moreover, in practice and in the hospitals where it pushes its CTPs, Defendant routinely refers to its "over 470" contractor clinicians as "influencers" and Defendant openly recruits them from the ranks of the hospitals where it pushes its products.

32. By remunerating these clinicians as "influencers", Defendant violates 42 USC §1320a-7b(b)(3)(C)(i) and (ii) in the following ways:

a. The "influencers" are paid a fee of $150 per CTP unit prescribed but are not persons who are authorized to act as purchase agents for the Hospitals. This payment is made pursuant to a "training request and invoice" submitted by the "influencer" to Tactile Medical. Attached hereto as Exhibit "E" is a true and correct copy of such a "training request and invoice."

b. The "influencers" are paid a fee of $150 per CTP unit prescribed but do not have written contracts with the Hospitals or other entities that are providers of services.

c. Defendant does not disclose to the entities that are providers of services the amounts received from Defendant with respect to CTP purchases made by or on behalf of the entity.

d. Defendant offers to pay and does pay its "influencers" $150 as a "fee" to induce these persons to arrange for the furnishing of the CTP devices and disguises this as a "delivery fee" of Defendant's CTPs to patients.

e. Defendant does not disclose its payments to "influencers" to the Government, in its 10-k or to Medicare, Medicaid or the Hospitals.

33. The Hospitals in Houston, Sugarland and The Woodlands account for over 80% of the patients for whom Defendant's equipment is provided in this District. None of the Hospitals has been informed of the kickbacks which Defendant pays to their clinicians, all of which occur under the radar and without Hospital sanction. Moreover, the facilities implicated are home to Houston's largest lymphedema clinics and wound care centers.

34. As a prescribing facility, the Houston VA Hospital was one of Relator VFMS' main sources of revenue in Houston until Defendant began its illegal activities as alleged herein. Starting 2017, Defendant began to take orders away from Relator VFMS. Doctors would switch their orders to Defendant without any notice to VFMS and when VFMS enquired of hospital staff, the staff members confirmed that they had begun ordering from Defendant because they were the Defendant's "contractors" who received compensation from the Defendant for each pneumatic pump ordered.

35. Thus, as sales began to dwindle, VFMS learned that Defendant was paying Hospital clinicians a fee of $150 plus mileage for each pneumatic pump prescription the clinician actually delivered and set-up in the patient's home.

36. The hospitals' Medial Directors are aware that these staff are being paid by the Defendant.

37. By effectively using bribes and kickbacks, Defendant has successfully pushed Relator VFMS out of the hospitals in Houston, prescribing only Defendant CTPs in direct violation of 42 USC 1320a-7b and clearly articulated CMS conflict of interest policies as defined in FAR 3.1101 and as articulated in FAR 2.101 and FAR 9.502.

38. In addition, the Sugarland Hospital conducts a major lymphedema clinic and wound care business which had been a top prescriber of Allen and Gibbs until 2017 when Defendant began taking all of that business, by paying fees to hospital staff.

39. When the physician who owned his business then sold it to the Methodist Hospital in Sugarland, the physician joined its staff as a vascular specialist. This physician admitted to Relator VFMS' Jody Allen that he was now a paid spokesman for Defendant and this was the reason he was "supporting" its products and prescribing compression pumps only from Defendant.

40. The physician at the Sugarland hospital also told Allen that he would continue to do so, would continue to give paid speeches/presentations to colleagues, and would continue to influence the ordering of Defendant's branded equipment.

41. These statements are admissions of violations of 42 USC 1320a-7b and clearly articulated CMS conflict of interest policies as defined in FAR 3.1101 and as articulated in FAR 2.101 and FAR 9.502.

42. Significantly, all pneumatic compression pump devices qualify for Medicare funding and are assigned reimbursement codes of E0651 and E0652 without regard to the manufacturer.

43. In order to obtain payment from Medicare, a physician's certification is required on form CMS-846. It reads as follows:

> **SECTION C: Narrative Description of Equipment and Cost**
>
> (1) Narrative description of all items, accessories and options ordered;
> (2) Supplier's charge; and
> (3) Medicare Fee Schedule Allowance for each item, accessory, and option.
> (see instructions on back)
>
> **SECTION D: PHYSICIAN Attestation and Signature/Date**
>
> I certify that I am the treating physician identified in Section A of this form. I have received Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.

44. The submission of every form CMS-846 for Defendant CTP devices, without disclosure of the remuneration Defendant pays to the Hospital clinical staff, is a violation of 31 U.S.C. 3729(a)(1)(C) and (G).

45. This is because in requesting and receiving funds directly and indirectly from the United States, Defendant conspires with and causes the Hospitals and prescribing physicians to make false certifications in violation of 31 U.S.C. 3729(a)(1)(A) and to falsely conceal its illegal kickbacks in violation of 31 U.S.C. 3729(a)(1)(G).

46. The payment and/or offers of payment of remuneration by Defendant to Hospital clinical staff to induce them to purchase, order or arrange for or recommend purchase, or order of Defendant's CTP devices is a violation of 42 U.S.C. 1320a-7b (b)(2)(B) because such payments are knowingly and willfully made in return for purchasing, ordering, arranging or recommending purchasing or ordering CTP equipment from Defendant under the Medicare and Veterans programs.

47. In requesting and receiving funds directly and indirectly from the United States, Defendant conspires with and causes the Hospitals and prescribing physicians to make false certifications in violation of 31 U.S.C. 3729(a)(1)(A) and to falsely conceal its illegal kickbacks in violation of 31 U.S.C. 3729(a)(1)(G).

48. The material fact concealed in connection with the submission of the form CMS-846 is the illegal kickbacks paid to hospital clinicians

49. Defendant is liable to the United States under the FCA because of its knowing and willful offers to pay and payment of remuneration, directly or indirectly, overtly or covertly, in cash or in kind to Hospital clinical staff and physicians in order to induce such persons to purchase, order, or arrange for or recommend purchasing, ordering CTP equipment for which payment may

be made in whole or in part under a Federal health care program, in violation of 42 U.S.C. 1320a-7b (b)(2)(B).

50. The remuneration paid or offered to be paid by Defendant consists of "delivery fees" to Hospital clinical staff, and the payment or offer of payment of speaking fees and endorsement fees to Hospital physicians. Such payments are illegal kickbacks.

51. In addition, Defendant conspires with and causes the Hospital clinical staff and prescribing physicians to falsely certify compliance with Medicare reimbursement requirements through the false submission of forms CMS-846.

52. Defendant also conspires with and causes the Hospitals and prescribing physicians to engage in a pattern and practice of organizational and personal conflicts of interest as described herein.

53. As a result of the above, the Veterans Hospital was required to set acquisitions of CTP equipment aside for exclusive competition among service-disabled veteran-owned small business concerns like Relator VFMS, as well as to make sole source awards to service-disabled veteran-owned small business concerns under 13 C.F.R. 125.8-125.10. Relator VFMS was entitled to receive sole source awards from the Veterans Hospital in Houston but was, in fact, denied any awards whatsoever because of Defendant's illegal activities as described herein.

54. Because of the illegal financial rewards paid or offered to be paid by Defendant to employees of the Veterans Hospital in Houston, the Veterans Hospital in Houston was induced to ignore and did ignore Relator VFMS' status as a Service-Disabled Veteran Owned Small Business and it illegally refused to deal with Relator VFMS in violation of 31 U.S.C. 3730(h).

55. Defendant conspired with and induced the Veterans Hospital clinical staff and physicians to violate 31 U.S.C. 3730(h) to refuse to deal with Relator VFMS to Relator VFMS' substantial damage.

56. *Big Spring, Texas Veterans Hospital*. Defendant engages in the payment of illegal kickbacks to its "influencers" in a routine and systematic way, disguising its kickbacks as payments for "deliveries" of its equipment to patients. In exchange, Defendant makes it clear to its influencers that it expects the influencers to cause more and more Tactile compression pumps to be prescribed by the doctors for whom the influencers work. As an example, at the Big Spring, Texas Veterans hospital, Defendant engages a full-time Veterans employee/nurse to routinely provide "deliveries" for Defendant in exchange for illegal kickbacks from Defendant.

57. Following Defendant's normal protocol, this particular nurse "moonlights" for Defendant while on VA payroll but in reality, she is being paid by Defendant to do the very same job that she is paid to do by the Veterans hospital. In exchange for payments from Tactile, the nurse successfully caused the VA hospital to increase its purchases of compression pump devices from Tactile Medical from roughly $100,000 in 2016 to approximately $500,000 in 2017.

58. The aforementioned VA nurse went to the home of one patient to deliver the Tactile device but was told by the patient that he did not want the device. He stated he did not want the device because he is an over-the-road trucker without enough room in the cab of his truck for such a device. Despite this, the nurse, acting on behalf of Defendant, insisted that the patient take the device. The patient provided this information to administrative personnel at the Big Spring Veterans hospital.

59. When the Big Spring VA nurse's activities on behalf of Defendant became known to administrative personnel at the hospital, Tactile was barred from entering the hospital premises.

Despite being barred, Defendant's sales representative brazenly continued to enter the hospital premises where he would engage in aggressive "sales activities", including what administrative personnel referred to as "badgering" the doctors and getting them to order or prescribe Defendant's products. In some cases, Defendant's representative put on a white coat, walked in one of the clinics pretending to be a doctor – which he is not – and told patients that they needed a compression pump for their legs.

60. The aforementioned nurse and was the subject of ethics charges on two separate occasions as a result of her acceptance of money for doing "deliveries" on behalf of Defendant. According to VA administrative personnel, on both occasions the charges against the nurse were swept under the rug and the nurse continues to work at Big Spring VA. Moreover, the nurse continues influencing the ordering of these devices and she continues to make deliveries for Defendant for a fee. However, as a result of the efforts of certain administrative personnel at the Big Spring VA hospital, Defendant's orders were reduced from $500,000 to $100,000 in 2018.

V. CAUSES OF ACTION

COUNT I:
VIOLATIONS OF 42 U.S.C. § 1320a-7b

61. Relator VFMS re-alleges and incorporates by reference the allegations made in the preceding paragraphs of this Complaint as though fully set forth herein.

62. Defendant's conduct violates 42 U.S.C. §1320a-7b:

a. Defendant pays prescribing doctors to be "advisors" and paid spokespersons for its CTP devices, as alleged herein.

b. Defendant pays illegal remuneration to "influencers". Defendant fraudulently labels these payments "delivery fees" but these payments are, in fact, made to

induce these persons to refer patients or to purchase or recommend for purchase Defendant's CTPs in violation of 42 U.S.C. §1320a-7b(b)(2)(A) and (B).

63. Defendant need not have actual knowledge of 42 U.S.C. §1320a-7b or specific intent to commit a violation of this section. However, Defendant acted knowingly and touts its "evolving home care delivery model" featuring its use of "hospital clinicians" as it states in its 10-K. Defendant's ongoing violations of 42 U.S.C. §1320a-7b are integral and fundamental to its business.

64. The States operate Medicaid programs under federal and state laws and regulations. Claims paid by the States' Medicaid programs to Medicaid providers effectively use both federal and state funds. Medicaid is a federal health care program to which the Anti-Kickback Statute applies.

65. Providers participating in the Medicaid program are required to sign various agreements or certifications that are submitted to state Medicaid programs. Defendant and the relevant clinicians expressly or impliedly certified as a condition of payment that they would comply with applicable federal and state laws or regulations, including the Anti-Kickback Statute and similar state prohibitions on kickbacks. These certifications rendered the claims submitted by the Defendant and the relevant clinicians in connection with the kickback scheme false.

66. None of the claims submitted by Defendant and the relevant clinicians to Medicare and Medicaid in connection with Defendant's kickback arrangements was eligible for payment.

67. Accordingly, Defendant knowingly caused the submission of each of those false claims. Defendant also knowingly conspired with the relevant clinicians and other insiders to make each of those false claims.

68. In addition, Relator VFMS has been directly harmed by Defendant's schemes because orders for pneumatic compression devices which were earmarked for other companies are altered by clinicians and other insiders at medical facilities in order to divert the business to Defendant.

COUNT II
THE FALSE CLAIMS ACT, 31 U.S.C. §§3729(a)(I),(a)(2) and 3732 (b)

69. Relator VFMS re-alleges and incorporates by reference the allegations made in the preceding paragraphs of this Complaint as though fully set forth herein.

70. Originally enacted in 1863, the False Claims Act ("FCA") (1986) is "the primary vehicle by the Government for recouping losses suffered through fraud."[10]

71. The FCA prohibits any "person" from "knowingly present[ing], or caus[ing] to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval." 31 U.S.C. 3729(a)(1).

72. The Act also prohibits a variety of related deceptive practices involving government funds and property. 31 U.S.C. 3729(a)(2)-(7).

73. A "person" who violates the FCA "is liable to the United States Government for a civil penalty of not less than $5,500 and not more than $11,000, as adjusted by law, plus three times the amount of damages which the Government sustains." 31 U.S.C. 3729(a).

74. The Act authorizes Relator VFMS to bring an action on behalf of the United States and to share in any recovery. Relator specifically pleads for the maximum share of recovery allowed by law.

[10] H.R. Rep. No. 660, 99th Cong., 2d Sess. 18 (1986).

75. Relator claims treble damages under the False Claims Act, 31 U.S.C. §§ 3729, et seq. as amended.

76. Relator VFMS seeks to recover on behalf of the United States, damages and civil penalties arising from false and improper claims for payment that Defendant submitted, or caused to be submitted to Medicare, and for illegal kickbacks paid by Defendant, in connection with orders for Durable Medical Equipment, specifically, Compression Therapy Products from June 2012 to at least the date of filing of this Complaint.

77. Additionally, Relator VFMS seeks to recover on behalf of itself, damages and penalties arising from retaliatory actions committed against it by Defendant and its agents because of lawful acts done by Relator VFMS in furtherance of this action or other efforts to stop one or more violations of the FCA.

78. Through the acts described above, Defendant knowingly submitted or caused to be submitted to the United States government false or fraudulent claims for payment under a Federal health care program.

79. The United States, unaware of the falsity, paid the Defendant for claims that would otherwise not have been allowed.

80. By reason of the Defendant's fraudulent acts, the United States government has been damaged and continues to be damaged in the amount of millions of dollars. The very real issue of over-utilization of products marketed by Defendant continues to grow as the Defendant aggressively seeks individuals within these medical facilities to facilitate a corrupt business plan.

81. Therefore, Relator VFMS demands TRIAL BY JURY and judgment against Defendant for all monetary and equitable relief available under at law, including but not limited to

actual damages, trebled damages, statutory penalties, prejudgment and postjudgment interest, attorneys' fees and costs.

82. In addition, Relator VFMS requests such other and further relief to which it is or may be entitled.

COUNT III:
THE FALSE CLAIMS ACT, 31 U.S.C. §3730(h)

83. VFMS re-alleges and incorporates by reference the allegations made in the preceding paragraphs of this Complaint as though fully set forth herein.

84. VFMS was threatened, interfered with, harassed and discriminated against by Defendant; i.e., being unlawfully boycotted by the Veteran's Hospital in Houston and elsewhere, because of lawful acts done by it in furtherance of other efforts to stop one or more violations of the FCA.

85. As a result, VFMS is entitled to the relief provided for by 31 U.S.C. §3730(h)(2).

86. Therefore, VFMS demands judgment against Defendant for damages to compensate it for the contract it would have been awarded but for the discrimination, two times the amount of such damages, interest, and compensation for any special damages sustained by VFMS as a result of the discrimination, including litigation costs and reasonable attorneys' fees. VFMS requests such other and further relief to which it is entitled.

VI. DAMAGES

87. Defendant has committed thousands of violations of federal law, as alleged herein. Each payment made by Defendant to an "influencer" is a separate violation of 42 U.S.C. §1320a-7b and each such payment subjects Defendant to a minimum penalty of $5,500. Defendant therefore is liable to the United States Government for penalties of at least $5,500 for each payment

to an "influencer." Defendant also is liable for actual damages for all fraudulently obtained payments, i.e., sales of CTPs. Defendant also is liable for treble damages, attorney fees and costs, and all other relief provided by law.

VII. JURY DEMAND

88. VFMS demands trial by jury.

Respectfully Submitted,

/s/ J. Mark Brewer

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CERTIFICATE OF SERVICE

A copy of this Qui Tam Complaint has been served on October 6, 2020 in accordance with 31 U.S.C. 3730(b)(2), as follows:

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